

Attachment A

Informed Consent

NOTE TO REVIEWERS

Font size has been changed in some sections in order to fit into the protocol document. All questionnaire forms will be professionally formatted before printing. Font type and size may change to make the questionnaires easier to read.

Readability has been calculated using the Flesch-Kincaid method for determining grade level at the 7.8th grade level when sentences containing agency names are omitted. Agency names are defined the first time they are used and acronyms are used thereafter.

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
DIVISION OF ENVIRONMENTAL AND OCCUPATIONAL EPIDEMIOLOGY
LANSING, MICHIGAN**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
ATLANTA, GEORGIA**

ADULT CONSENT TO BE IN AN EXPOSURE INVESTIGATION

What We Are Doing

The Michigan Department of Community Health (MDCH) in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR) is doing an investigation of dioxin levels in people that are currently living on the flood plain of the Tittabawassee River. The purpose is to document the extent of their exposure to dioxin and dioxin-like chemicals in the environment.

Dioxin is a name given to a family of similar chemicals. Dioxins are found in the air, water, soil and food. Dioxins are not made on purpose. They come from burning fuel, wood and waste and from making certain products. When dioxins get in the environment, they do not break down easily. They do not dissolve in water and they do not evaporate in air. When they get in your body they stay for a long time in your blood and body fat. Everyone has some dioxin in his or her body.

Why We Are Doing This Investigation

The purpose of the investigation is to find out if the levels of dioxin in the blood of some people who live on the flood plain of the Tittabawassee River are different than people who live in other areas of the country. If we find differences, we will look to see if the people with higher levels have anything in common. We will look at the levels of dioxins in soil at their property, the level of dioxins in dust in their homes, and whether they eat fish from the river or game from the flood plain to see if these factors are associated with higher levels of dioxin in people's blood.

Why You Are Being Asked to Be in this Investigation

You have been chosen for this investigation because you live in the flood plain of the Tittabawassee River, you are the right age, and you are able to give a blood sample. The Michigan Department of Environmental Quality (MDEQ) has already taken soil samples from your yard to find out if your property is contaminated with dioxin. The MDEQ has sent you a letter telling you of your soil test results. We are asking you to be in this investigation to help us find out if the levels of dioxin in the blood of people who live on the flood plain of the Tittabawassee River are different than people who live in other areas of the country.

What We Will Ask You to Do

You are free to join the investigation or not. If you join the investigation, you are free to stop at any time. You may stop by telling the person drawing your blood or taking dust samples to stop doing so. Or you may contact the Principal Investigator, Linda D. Dykema, at 517-335-8566 or 1-800-648-6942 even if blood and dust samples have already been taken. If you join the investigation, we will withdraw some blood from your arm and take dust samples from several areas of your home. We will also be asking you some questions about your occupation and personal habits.

What We Will Do

We will first ask you some questions to verify that you can safely give blood, thus making you eligible for the investigation. Then:

1. A person trained to draw blood will take 80 ml (about 5 ½ tablespoons) of blood from a vein in your arm. Your blood will be collected in eight 10-ml tubes.
2. A staff person will ask you questions about where you have lived, worked, and what foods you eat.
3. A staff person will take indoor dust samples from several areas of your home using a special vacuum.

How Long it Will Take

It should take about two hours to complete the blood test, questions, and indoor dust sampling. You will only have to give a blood sample once.

Contacting You in the Future

We will send you a letter with your blood and indoor dust test results. The letter will have a number for you to call if you have any questions. If we find any pattern of exposure, we may contact you to ask additional questions sometime in the future. If you agree to allow us to contact you, we will explain our questions to you and you can decide to consent to answer them or not in the same way you are doing now.

What We Will Do with Your Blood

For this investigation we will look at your blood for dioxins and dioxin-related chemicals. Dioxin levels are reported on a lipid-weight basis, so your blood lipid content will be determined. We will not test your blood for anything else.

What the Investigation Will Tell us

1. The level of dioxin that you have in your blood.
2. The level of dioxin in dust in your home.
3. If the level of dioxin in your blood is different from the level in other people's blood.

What the Investigation Will NOT Tell Us

1. Where the dioxins came from, if they are found.
2. Information on chemicals other than dioxin and other dioxin-like chemicals.
3. If you will get sick from the level of dioxin in your blood.

Risks

We will try to make you as comfortable as possible but taking your blood may hurt a little. You will feel a slight "pinch" when we put the needle in. Some people may faint, but this is rare. You may also feel some discomfort during the sampling and/or later see a small bruise where the blood was drawn from.

Benefits

You will receive a copy of your dioxin test results and, if you desire, a copy will also be sent to your physician. You will receive some fact sheets about dioxins and you will assist in the answering of questions about the amount of dioxin in the blood of people who live on the flood plain of the Tittabawassee River. If you decide not to participate in this investigation the fact sheets will still remain available to you.

Compensation

You will not receive any payment for joining the investigation. There will be no cost to you for joining the investigation.

If You Do Not Want to Be in the Investigation or If You Change Your Mind Later

You can refuse to have your blood drawn or to answer any survey questions at any time. There is no penalty for this decision. You may choose to leave this investigation at any time, even after you have signed the consent form.

Privacy

Your name and test results will be kept private to the extent allowed by the law. Your name will not be used in any reports written about this investigation. Any reports that are written about the investigation will only use dioxin levels. All names and test results will be kept in a locked file. Only the contact person shown below will have access to these files.

Contact Person

If you have any question about the investigation, or wish to withdraw from the investigation, please contact:

Linda D. Dykema, Principal Investigator
Michigan Department of Community Health
P.O. box 30195
Lansing, Michigan 48909
Direct: 517-335-8566
Toll-free: 1-800-648-6942

For questions regarding research subjects' rights, please contact:

Dr. Robin Wagner, Deputy Associate Administrator for Science
Agency for Toxic Substances and Disease Registry
1600 Clifton Road E-31
Atlanta, Georgia 30333
Direct: 404-498-0003
Toll-free: 1-888-422-8737 Extension 0003

If you do not understand this investigation or what we are asking you to do, please ask questions. If you have no questions and if you agree to be in this investigation, please sign the consent form below.

PARTICIPANT CONSENT

By signing this consent form you are stating that you have read and/or been told about the Pilot Exposure Investigation purpose, questions, and the blood and indoor dust samples that will be taken. You are also affirming that you have been given a chance to ask questions, that your questions have been answered, and that you have been given a copy of this form. By signing this consent form you are agreeing to participate in this investigation. However, being in the investigation is your free choice and you can discontinue your participation at any time without penalty of any kind. Please answer the following question by indicating your response.

May we take an 80 ml (eight 10 ml tubes) sample of your blood for dioxin/furan and lipid analysis? YES _____ NO _____	May we collect indoor dust from your home for dioxin/furan analysis? YES _____ NO _____	May we ask you questions about where you have lived, worked, and what foods you eat? YES _____ NO _____
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Please answer the following question by indicating your response. Your answer will not disqualify you from the investigation. If you grant us permission to contact you in the future, you are NOT also promising to answer any questions. If we decide to contact you in the future, we would again ask your permission to question you at that time.

May we contact you in the future if we have additional questions? At that time we will ask you for your consent again.

YES _____ NO _____

Participant Name (Print)

Participant's Signature

Date

If you would like a copy of your dioxin blood test results to be sent to your doctor, please complete the instructions for contacting your doctor below:

Name: _____ Telephone Number: _____

Address: _____

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
DIVISION OF ENVIRONMENTAL AND OCCUPATIONAL EPIDEMIOLOGY**

**Pilot Exposure Investigation Eligibility Questionnaire
Tittabawassee River, Michigan**

1. Name			
Last	First	Middle	
2. Age: _____ Years	Date of Birth: _____ Month/Day/Year		
3. Sex (circle) Male Female			
Address			
Number	Street	Apt.	City Zipcode
4. Telephone Number(s)			
5. Have you lived at your current residence in the flood plain of the Tittabawassee River for the last 5 years?		Yes	NO - Ineligible Thank you for your time. In order to participate in this investigation you must have lived on the flood plain of the Tittabawassee River for the last 5 years.
6. Do you have hemophilia or any other blood clotting or bleeding disorder?		YES - Ineligible Thank you for your time. In order to participate in this investigation you must be eligible to give a blood sample. Your "Yes" answer makes you ineligible to give blood.	No
7. Have you received chemotherapy in the past 6 wks?			No
8. Do you weigh less than 95 pounds?			No
9. Have you lost more than 15 lbs. In the last year?			No
- - - - - For Women Only - - - - -			No
10. Are you currently pregnant?			No
11. Have you breast-fed a child in the past 6 months?			No
12. Would you be willing to consider participating in this investigation of dioxin exposure by having some blood drawn and analyzed?		Yes	No
			I need more info. Schedule follow-up call

Appointment scheduled for:

Date

Time

Location

Follow-up call scheduled for:

Date

Time
